IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

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CV 13 - 0516

CIVIL ACTION NO:_____

RICHARD PHELPS and
BONNIE PHELPS,

Plaintiffs,

vs.

COMPLAINT AND DEMAND FOR JURY TRIAL

MERCK & CO., INC.;
MERCK, SHARP, DOHME CORP.;
MEDICAL HAIR RESTORATION, INC.;
BOSLEY, INC. (as successor-by-merger to MEDICAL HAIR RESTORATION, INC.);
and BOSLEY MEDICAL GROUP, S.C.
(as successor-by-merger to MEDICAL HAIR RESTORATION, INC.),

GLEESON, J.

Defendants.

----------X POHORELSKY, M.J.

This case relates to:

MDL No. 1:12-MD-02331-JG-VVP

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Plaintiffs, Richard Phelps and Bonnie Phelps, by and through undersigned counsel, and as their Complaint state and bring this civil action before the Court for the United States District Court for the Eastern District of New York as a related action in the matter entitled *IN RE: PROPECIA (FINASTERIDE) PRODUCTS LIABILITY LITIGATION*, MDL No. 2331, against the Defendants Merck & Co., Inc. and Merck Sharp Dohme Corp. (collectively "Merck") and allege as follows:

INTRODUCTION

1. This is an action for damages against Defendants. The allegations, claims, and theories of recovery relate to Defendants' designing, manufacturing, testing, marketing, labeling, advertising, promoting, supplying, distributing, selling, and/or placement of the unsafe prescription drug finasteride, which is sold by Defendants under the trade name Propecia® ("PROPECIA") (finasteride 1 mg) and Proscar® ("PROSCAR") (finasteride 5 mg), into the stream of commerce.

2. Although finasteride is prescribed in the 5 mg dose to treat Benign Prostatic Hyperplasia ("BPH") (commonly referred to as an enlarged prostate), PROPECIA and PROSCAR are also prescribed for androgenic alopecia—otherwise known as male pattern hair loss or male pattern balding.

3. Male pattern hair loss is a naturally occurring normal male phenomenon.

4. PROPECIA and PROSCAR are associated with and cause certain sexual side effects in users, including: loss of libido; erectile dysfunction; impotence; testicular pain; decreased semen output; orgasm disorders; ejaculation disorders; male infertility; and poor semen quality. Additionally, PROPECIA and PROSCAR are associated with and cause mental, cognitive, and emotional issues, such as: depression; anxiety; memory loss; problems with cognitive processing or "brain fog;" and suicidal ideation. PROPECIA and PROSCAR are associated with and cause sleep disturbances; Peyronie's disease and other penile deformities; fatigue and lethargy; male breasts (gynecomastia); an increased risk of male breast cancer; and a form of high grade prostate cancer.

5. At all times relevant, Defendants are and were liable for injuries caused by PROPECIA and PROSCAR, as the manufacturers, suppliers, and/or sellers of PROPECIA and PROSCAR and/or for their negligence and activities in labeling, advertising, promoting, marketing,

distributing, supplying, selling, and/or otherwise placing into the stream of commerce PROPECIA and PROSCAR.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds $75,000, exclusive of interests and costs, and because there is complete diversity of citizenship between Plaintiff and Defendants.

7. Venue is proper in this judicial district pursuant to this Court's Practice and Procedure Order No. 3, in *IN RE: PROPECIA (FINASTERIDE) PRODUCTS LIABILITY LITIGATION*, MDL No. 2331, entered on September 12, 2012, in any case filed directly in the Eastern District of New York that would have otherwise been properly transferable to this Multi-District Litigation proceeding and for which the original venue would have otherwise been proper in a district court outside the Eastern District of New York.

8. Plaintiffs further state that, but for this Court's Practice and Procedure Order No. 3, Plaintiffs would have filed their case in the Southern District of Ohio where Plaintiffs reside; where the events giving rise to the claims occurred; and where Defendants conduct business and market, advertise, promote, distribute, receive substantial compensation and profits from sales, and other acts that caused or contributed to the harm giving rise to Plaintiffs' action and Defendants to personal jurisdiction in that District.

9. Upon the completion of all MDL pretrial proceedings applicable to this case and consistent with this Court's Practice and Procedure Order No. 3, Plaintiffs seek remand of this case for trial to the United States District Court for the Southern District of Ohio, which district is the proper venue under 28 U.S.C. § 1391 (a & c) because the events giving rise to the claims occurred within that District and because Defendants conduct business within that District and have engaged

in advertising, promoting, marketing, supplying, distributing, and/or selling goods and products to consumers in that District.

PARTIES

10. Plaintiff Richard Phelps is a 60 year old male who, at times relevant to the events described herein, was a resident of Franklin County, Ohio residing at 6414 Graessle Road, London, Ohio 43140.

11. Plaintiff Bonnie Phelps is married to Richard Phelps who, at times relevant to the events described herein, was a resident of Franklin County, Ohio, residing at 6414 Graessle Road, London, Ohio 43140.

12. Defendant Merck & Co., Inc. (along with Merck Sharp Dohme Corp., collectively referred to as "Merck") is a New Jersey corporation with their principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

13. Defendant Merck Sharp & Dohme Corp. (along with Merck & Co., Inc., collectively referred to as "Merck") is a New Jersey corporation with their principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

14. Defendant Bosley, Inc. (along with Defendant Bosley Medical Group, S.C. collectively referred to herein as "Bosley") is a Delaware corporation with its principal place of business in California at 9100 Wilshire Boulevard, East Tower Penthouse, Beverly Hills, California 90212. Bosley has a business location in the state of Ohio at 425 Metro Place North, Suite 175, Dublin, Ohio 43017, a former Medical Hair Restoration, Inc. office location prior to Medical Hair Restoration, Inc.'s merger with Bosley. Plaintiff was a customer at this location and was prescribed and supplied PROPECIA through this office location. Bosley supplies, sells, advertises,

promotes, markets, and/or otherwise places into the stream of commerce PROPECIA through its various office locations and on its website, www.bosley.com.

15. Defendant Bosley Medical Group, S.C. (along with Defendant Bosley, Inc., collectively referred to herein as "Bosley") is a Illinois corporation with its principal place of business in California at 9100 Wilshire Boulevard, East Tower Penthouse, Beverly Hills, California 90212. Bosley has a business location in the state of Ohio at 425 Metro Place North, Suite 175, Dublin, Ohio 43017, a former Medical Hair Restoration, Inc. office location prior to Medical Hair Restoration, Inc.'s merger with Bosley. Plaintiff was a customer at this location and was prescribed and supplied PROPECIA through this office location. Bosley supplies, sells, advertises, promotes, markets, and/or otherwise places into the stream of commerce PROPECIA through its various office locations and on its website, www.bosley.com.

16. Defendant Medical Hair Restoration, Inc. ("MHR") is a Delaware corporation with its principal place of business in Florida at 2600 Lake Lucien Drive, Suite 180, Maitland, Florida 32751 that, according to Defendant Bosley's website, merged with Bosley effective June 1, 2010. The Ohio Secretary of State records showing Bosley and MHR's merger were filed on August 23, 2010. MHR had a business location in the state of Ohio at 425 Metro Place North, Suite 175, Dublin, Ohio 43017, where Plaintiff was a customer and was prescribed and supplied PROPECIA. MHR supplied, sold, advertised, promoted, marketed, and/or otherwise placed into the stream of commerce PROPECIA through its various office locations and on its website www.medicalhairrestoration.com (now automatically redirected to: http://www.bosley.com/bosley_and_mhr.php).

17. At all times relevant herein, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed,

distributed, supplied, sold, and/or otherwise placed into the stream of interstate commerce the prescription drugs, PROPECIA and/or PROSCAR, and throughout the Southern District of Ohio. At all times relevant herein, Defendants were registered to do business in the Southern District of Ohio.

GENERAL FACTUAL ALLEGATIONS

A. Design, Approval, and Initial Promotional Efforts of PROPECIA for Male Pattern Hair Loss

18. On or about December 1996, Merck filed New Drug Application ("NDA") No. 20-788. The finasteride tablets described in NDA No 20-788 are prescribed to address androgenic alopecia or male pattern hair loss and sold in the United States under the trade name "PROPECIA®." The United States Food & Drug Administration ("FDA") first granted approval for 1 mg, including the active ingredient finasteride, for male pattern hair loss in December 1997.

19. PROPECIA contains 1 mg of the active ingredient, finasteride, and is a lower dose version of Merck's PROSCAR, which contains 5 mg of finasteride. Merck markets PROSCAR for the treatment of symptomatic benign prostatic hyperplasia ("BPH")—commonly referred to as enlarged prostate.

20. PROSCAR had been on the market for some years for the treatment of BPH but went off patent and lost its market exclusivity in the United States in June of 2006. As a result, Merck realized a significant decline in U.S. PROSCAR sales. While the basic patent for PROSCAR also covers PROPECIA, additional patents that do not expire until October 2013 continue to protect Merck's market exclusivity for PROPECIA.

21. Defendants Merck market PROPECIA as a prescription drug for men with androgenic alopecia or male pattern hair loss or male pattern balding.

22. PROSCAR is often also used as a "less expensive" alternative to the costly PROPECIA for male pattern hair loss whereby men split the 5 mg finasteride pills into quarters, generally taking a one quarter portion of the pill once daily.

23. Male pattern hair loss is neither an illness nor a disease; rather, it is a healthy normal occurrence.

24. Male pattern hair loss or balding is a naturally occurring normal male phenomenon. Testosterone driven male pattern hair loss is attributed to a combination of genetic factors and a hormone, called dihydrotestosterone (DHT). DHT is believed to contribute to shortening the growth phase of and to thinning of the hair.

25. Merck states that finasteride is a type II 5-α reductase inhibitor that prevents the conversion of androgen testosterone to DHT in the scalp leading to a reduction of hair loss.

26. Because male pattern hair loss is a cosmetic concern for men and neither an illness nor a disease, Merck developed and implemented an aggressive direct-to-consumer marketing and advertising campaign focused at men who had experienced or were experiencing male pattern hair loss or men who were generally concerned about losing their hair.

27. In describing its direct-to-consumer advertising and marketing strategy for PROPECIA, Merck's Dermatology Therapeutic Business Group identified PROPECIA as a "cosmeceutical" product.

28. In 1998, Merck spent $60 million in a direct-to-consumer advertising campaign for PROPECIA. In 1999, Merck spent $125 million in direct-to-consumer advertising for PROPECIA. In recent years, Merck has spent upwards of a billion dollars per year advertising its various drugs.

29. Sales of PROPECIA have consistently increased over the past decade: $239MM in 2003; $270MM in 2004; $291MM in 2005; $351MM in 2006; $405MM in 2007; $429MM in 2008; $440MM in 2009 and $447MM in 2010.

B. Merck Fails to Warn U.S. Consumers of the Risk of Chronic Sexual Side Effects from PROPECIA

30. At all times relevant herein, Merck failed to warn consumers that the use of PROPECIA to treat male pattern hair loss could result in chronic sexual dysfunction, despite receiving adverse reports by PROPECIA users and prescribing and treating doctors of chronic sexual dysfunction beginning in the late 1990's.

31. In fact, Merck, at their marketing and information website for PROPECIA, www.propecia.com, denied and downplayed the serious and chronic nature of the adverse sexual events associated with the use of PROPECIA for male pattern hair loss.

32. Until April of 2012, at their marketing and information website for PROPECIA, www.propecia.com, Merck represented and warranted that:

> A small number of men had sexual side effects, with each occurring in less than 2% of men. **These include less desire for sex, difficulty in achieving an erection, and a decrease in the amount of semen. These side effects went away in men who stopped taking PROPECIA because of them.** (Emphasis added). In addition, these side effects decreased to 0.3% of men or less by the fifth year of treatment

33. Thus, Merck, at their marketing and information website for PROPECIA, www.propecia.com, denied and downplayed the serious and chronic nature of the adverse sexual events associated with the use of PROPECIA for male pattern hair loss by expressly warranting and representing that all sexual side effects "went away" upon discontinuation of PROPECIA. This representation and warranty was purposefully offered to encourage men to try PROPECIA for male pattern hair loss with no risk or concern of developing persistent and chronic side effects.

34. Also, at their marketing and information website for PROPECIA, www.propecia.com, Merck represented and warranted that:

> A small number of men experienced certain sexual side effects. These men reported one or more of the following: less desire for sex; difficulty in achieving an erection; and, a decrease in the amount of semen. Each of these side effects occurred in less than 2% of men. **These side effects went away in men who stopped taking PROPECIA. They also disappeared in most men who continued taking PROPECIA.** (Emphasis added).

35. Thus, Merck, at their marketing and information website for PROPECIA, www.propecia.com, denied and downplayed the serious and chronic nature of the adverse sexual events associated with the use of PROPECIA for male pattern hair loss by expressly warranting and representing that all sexual side effects "went away" upon discontinuation of PROPECIA and "also disappeared" in most men who continued taking the drug. These representations and warranties were purposefully offered to encourage men to try PROPECIA for male pattern hair loss with no risk or concern of developing persistent and chronic side effects and to encourage men to continue using PROPECIA, despite suffering serious and potentially chronic side effects.

36. Further, the PROPECIA entries in the Physician's Desk Reference ("PDR") (an annual, commercially published compilation of manufacturers' prescribing information) over the years since PROPECIA's entry into the market, written and submitted by Merck, have consistently stated that while PROPECIA users have experienced adverse experiences, particularly sexual, these side effects resolve or "go away" once a user stops taking PROPECIA or "disappear" with continued use of PROPECIA:

> **What are the possible side effects of PROPECIA?**
>
> Like all prescription drugs PROPECIA may cause side effects. In clinical studies, side effects from PROPECIA were uncommon and did not affect most men. A small number of men experienced certain sexual side effects. These men reported one or more of the following: less desire for sex; difficulty achieving an erection; and, a decrease in the amount of semen. **Each of these side effects occurred in**

> **less than 2% of men. These side effects went away in men who stopped taking PROPECIA. They also disappeared in most men who continued taking PROPECIA.** (Emphasis added).

37. Thus, Merck, in its PDR entries have consistently denied and downplayed the serious and chronic nature of the adverse sexual events associated with the use of PROPECIA for male pattern hair loss by expressly warranting and representing that all sexual side effects would "go away" upon discontinuation of PROPECIA or "disappear" with continued use of PROPECIA.

38. Additionally, the PROPECIA PDR entry states:

> Integrated analysis of clinical adverse experiences showed that during treatment with PROPECIA, 36 (3.8%) of 945 men had reported one or more of these adverse experiences as compared to 20 (2.1%) of 934 men treated with placebo (p=0.04). **Resolution occurred in all who discontinued therapy with PROPECIA due to these side effects and in most of those who continued therapy.** (Emphasis added). The incidence of each of the above side effects decreased ≤0.3% by the fifth year of treatment with PROPECIA.

39. Further, as to adverse experiences involving ejaculate volume, the PDR entry for PROPECIA states:

> In a study of finasteride 1 ml daily in healthy men, a median decrease in ejaculate volume of 0.3 mL (-11%) compared with 0.2 mL (-8%) for placebo was observed after 48 weeks of treatment. Two other studies showed finasteride at 5 times the dosage of PROPECIA (5 mg daily) produced significant median increases of approximately 0.5 mL (-25%) compared to placebo in ejaculate volume, **but this was reversible after discontinuation of treatment.** (Emphasis added).

40. These statements by Merck regarding PROPECIA are deceptive and misleading in that they fail to advise potential users of PROPECIA and prescribing doctors that numerous users of the product have reported suffering chronic sexual side effects even after discontinuing use.

41. Merck failed to adequately study, test, evaluate, and/or examine the chronic nature of PROPECIA's sexual side effects, let alone study, test, evaluate, and/or examine the other chronic side effects caused by the cosmetic hair loss drug.

42. In or about 2008, Merck changed the product warnings and instructions in Sweden to include the following warning:

> In addition, the following have been reported in post-marketing use: persistence of erectile dysfunction after discontinuation of treatment with PROPECIA.

43. In or about August 2009, the Swedish Medical Products Agency concluded that PROPECIA could lead to permanent erectile dysfunction.

44. In December 2009, the United Kingdom Medicine Health Care Product Regulatory Agency (MHRA) in its public assessment report on the risk of finasteride stated:

> In addition, the following have been reported in post-marketing use: persistence of [erectile dysfunction] after discontinuation of treatment with PROPECIA.

45. Subsequently, Merck changed the PROPECIA product warnings in the United Kingdom in December 2009 to include:

> In addition, the following have been reported in postmarketing use: persistence of erectile dysfunction after discontinuation of treatment with PROPECIA; male breast cancer (see 4.4 Special warnings and precautions for use).

46. In Italy, Merck revised the PROPECIA product warnings and instructions in March 2010, to include a warning of persistent erectile dysfunction after discontinuation of treatment.

47. As a result of the use of finasteride for male pattern hair loss, Merck and the FDA have received numerous reports of adverse events related to persistent sexual dysfunction after discontinuation of finasteride by users and prescribing and treating physicians as early as the late 1990's.

48. Though Merck revised the product monograph in the United States for finasteride on October 6, 2010, these revisions did not include the updated warning regarding the persistence of sexual dysfunction after discontinuation of use.

C. The Chronic Side Effects of PROPECIA and PROSCAR

49. Recently published studies in peer reviewed journals have revealed the true nature of the chronic nature of the side effects of using PROPECIA and PROSCAR for male pattern hair loss.

50. A 2003 study by *Wessels, et al.*, titled "Incidence and Severity of Sexual Adverse Experiences in Finasteride and Placebo-Treated Men with Benign Prostatic Hyperplasis," reported that only 50-59% of men who experienced sexual adverse effects after taking finasteride experienced resolution of the adverse events even after discontinuing use of finasteride.

51. A 2006 study by *Rahimi-Ardabili, et al.*, titled "Finasteride Induced Depression: A Prospective Study," reported that study participants given 1 mg of finasteride demonstrated a slight increase in anxiety and a significant increase in depression from using finasteride 1 mg. Because of the significant occurrence of depression from finasteride use, the study suggests that finasteride should be "prescribed cautiously," especially in patients who are "more susceptible to it."

52. A 2011 article by *Traish, et al.*, titled "Adverse Side Effects of 5α-Reductase Inhibitors Therapy: Persistent Diminished Libido and Erectile Dysfunction and Depression in a Subset of Patients," reported on the results of a seven year study:

> Clearly, the sexual adverse events do not necessarily resolve completely in all patients, who discontinue use of finasteride, again supporting the premise that in some patients these sexual side effects remain "persistent."
>
> …5α-RIs therapy, while improving urinary symptoms in patients with BPH and may prevent hair loss, produce significant adverse effects in some individuals including loss of libido, ejaculatory dysfunction, and potential depression.

53. A 2011 article by *Irwig, et al.*, titled "Persistent Sexual Side Effects of Finasteride for Male Pattern Hair Loss," reported:

> The prevalence of sexual dysfunction by item was 94% for low libido, 92% for erectile dysfunction, 92% for decreased arousal, and 69% for problems with orgasm. Most sexual dysfunction began while subjects were on finasteride, but some reported the onset shortly after discontinuing the medication.

> ...the mean duration of the persistent sexual side effects was 40 months, with 20% of subjects reporting durations of over 6 years. Most men developed sexual dysfunction in multiple domains with 94% experiencing low libido, 92% experiencing erectile dysfunction, 92% experiencing decreased arousal, and 69% experiencing problems with orgasm.

54. A 2012 article by *Irwig*, titled "Persistent Sexual Side Effects of Finasteride: Could They Be Permanent?," reported:

> In a group of 54 otherwise healthy former users of finasteride who developed persistent sexual side effects that lasted for at least 3 months, 96% continued to experience these effects when reassessed 9–16 months (mean 14 months) later, raising the possibility of permanent effects. Eighty-nine percent of subjects continued to meet the definition of sexual dysfunction according to ASEX ["Arizona Sexual Experience Scale"] (a test used to measure sexual dysfunction).

In addition to the sexual dysfunction experienced by the study's participants, the male study participants also reported:

> …a broad range of persistent signs and symptoms that point to the systemic effects of finasteride, as 5-α reductase is widely distributed throughout many organ systems. The most volunteered changes related to the urogenital system in terms of semen quality and decreased ejaculate volume, reduction in penis size, penile curvature or reduced sensation, fewer spontaneous erections, decreased testicular size, testicular pain, and prostatitis. Many subjects also noted changes to their mental abilities, sleeping patterns, and/or depressive symptoms. Many subjects reported a "disconnection" between the mental and physical aspects of sexual function.

55. A 2012 article by *Irwig*, titled "Depressive Symptoms and Suicidal Thoughts Among Former Users of Finasteride with Persistent Sexual Side Effects," reported that 11% of former finasteride (1 mg) users who used finasteride for male pattern hair loss exhibited mild depression, 28% moderate depression, and 36% severe depression, as measured by the Beck Depression Inventory ("a widely used validated instrument that measures the severity of depression in adults"). In comparison, 10% of the control group of men, who also experienced male pattern hair loss but never used finasteride, exhibited mild depression, with no participants in the control group

experiencing moderate or severe depression. Moreover, 39% of former users of finasteride reported suicidal thoughts, with 3% selecting the descriptive statement: "I would like to kill myself." In comparison, 3% of the control group admitted having suicidal thoughts. As a result of his study, Dr. Irwig cautioned that clinicians and potential finasteride users "…should be aware of the serious potential risks of [finasteride 1 mg], especially as it is being used cosmetically to alter a normal age-related process."

56. Physicians who treat men's health issues in the United States and Europe have publically expressed their concerns about patients who have chronic sexual, mental, and physical side effects after discontinuing finasteride. These physicians have posted information on their websites and have spoken at medical symposiums about the problem of chronic sexual dysfunction from the use of finasteride.

57. For Example, Dr. John Crisler, a physician at a men's health clinic in Michigan, stated:

> I am just totally against finasteride. I have had so many patients that have come to me where that medication has destroyed their life.
>
> ...They take finasteride for even as short as a week and it destroys their lives. And they become depressed, weak, impotent and the problem is when they go off the drug their symptoms remains.

58. Dr. Alan Jacobs, a neuroendocrinologist in New York has a blog addressing issues related to hormones, behavior and the brain at http://alanjacobsmd.typepad.corn/alanjacobsmds-blog/. In one of his posts in April 2010 titled "A Neuroendocrine Approach To Finasteride Side Effects In Men," he states:

> I have recently seen an increasing number of men who have developed significant degrees of clinical hypogonadism - low sex drive, erectile dysfunction, reduced sexual sensations and listlessness, fatigue and/or "brain fog" - while either taking finasteride or after stopping the medication, even long after stopping it.
>
> Finasteride certainly helps men fight hair loss and prostate enlargement. However, a considerable number of men have intolerable and sometimes

> persistent side effects from the medicine. A systematic neuroendocrine approach to this problem should shed light on the cause in a majority of cases and bring relief.

59. Dr. Andrew Rynne, a physician in Kildare, Ireland, who is a specialist in treating sexual dysfunction, has also spoken out about the risk of using finasteride. On the website for his clinic, http://doctorrynne.blogspot.com/, Dr. Rynne posted an entry titled "Male Pattern Baldness and Propecia" in which he writes about the problems he has seen in his patients who have taken PROPECIA:

> I want to shout this from the rooftops. However, I will shout it into cyberspace instead. I want the ear of every young man on this planet who may be experiencing testosterone driven male pattern balding. Please listen to me. Do NOT under any circumstances even for one minute consider taking the testosterone-suppressing drug Proscar or Propecia or Finasteride to give it its chemical name. The consequences of using this drug for male pattern balding can be life shattering.
>
> Here's what the manufacturers Merck say on their Patient's Product Information leaflet about Propecia:
>
> > "In clinical studies for Propecia, a small number of men experienced certain sexual side effects, such as less desire for sex, difficulty in achieving an erection, decrease in the amount semen produced. Each of these side effects occurred in less than 2% of men and went away in men who stopped taking Propecia because of them."
>
> What jumps out at you here is that figure 2%. However, even if you accept this figure as true, and personally I do not accept it, but even if you do, to the uninitiated it might seem like a low figure. But for 2% of men on Proscar to experience serious side effects like erectile dysfunction, loss of libido and reduced volume of semen this is actually a very high and significant figure.
>
> Remember you are dealing here with a naturally occurring normal male phenomenon called "Male Pattern Baldness." This is not an illness or a disease. This is a healthy normal occurrence. If in an attempt to "cure" it, you are getting a 2% rate of serious side effects, then that quite frankly is unacceptable.
>
> But here is the real lie that Merck is giving you in its Patient's Leaflet. Do you see that bit there about "went away in men who stopped taking Propecia - " That is simply not true and Merck know [sic] full well that it is not true. **They know it is not true because I and hundreds of other doctors and thousands of patients**

> **have told them that these side effects do not always go away when you stop taking Propecia.** (Emphasis added). We continue to be ignored of course. Merck is a multi-billion multinational company. In some cases men who have taken Proscar, even for a few months, have unwittingly condemned themselves to a lifetime of Sexual Anhedonia, the most horrible and cruel or all sexual dysfunctions.
>
> I have spoken to several young men in my clinic in Kildare who continue to suffer from sexual anaesthesia and for whom all sexual pleasure and feelings have been obliterated for all time. I have felt their suffering and shared their devastation. If you would like to learn more about this subject then visit them on www.propeciahelp.com. Please spread the word around. Taking Propecia for balding can have utterly disastrous consequences.

60. In a July 2011 editorial appearing in the Journal of Sexual Medicine [J Sex Med 2011;8:1829–1831], Irwin Goldstein, M.D., editor-in-chief of the Journal, stated:

> …I think of the frequent phone calls I receive from distressed men with varying degrees of hair loss who have used 5 alpha reductase inhibitors [such as Propecia] and now have newly manifested sexual and cognitive complaints that often persist despite discontinuation of the 5 alpha reductase inhibitor. Often such 5 alpha reductase inhibitor users have sought help elsewhere only to be belittled, betrayed, misdirected, and sometimes misinformed. In general, these patients feel deceived because of the lack of information warning them of potential sexual side effects. The majority feels strongly that the sexual problems are far worse than the hair loss concerns.

61. In March, 2011, FDA stated that "depression" is a potential adverse reaction to PROPECIA.

62. In April 2011, Merck included in their "Patient Product Information" for PROPECIA that users have reported "difficulty in achieving an erection that continued after stopping the medication." Also as of April 2011, Merck included in "Prescribing Information" for PROPECIA under the "Postmarketing Experience for PROPECIA" section that some users experienced "erectile dysfunction that continued after discontinuation of treatment."

63. In April 2012, the FDA ordered Merck to change the labeling for PROPECIA to include "libido disorders, ejaculation disorders, and orgasm disorders that continued after discontinuation

of the drug," as well as "decreased libido that continued after discontinuation of the drug" for PROSCAR. Additionally, the FDA required that both PROPECIA's and PROSCAR's label include "reports of male infertility and/or poor semen quality that normalized or improved after drug discontinuation."

64. In addition to the chronic sexual side effects caused by PROPECIA and PROSCAR, such as: loss of libido; erectile dysfunction; impotence; testicular pain; decreased semen output; orgasm disorders; male infertility; and poor semen quality, there are a number of additional chronic side effects of using the cosmetic hair loss drugs. These chronic side effects include mental, cognitive, and emotional issues, such as: depression; anxiety; memory loss; problems with cognitive processing or "brain fog;" suicidal ideation. Moreover, PROPECIA and PROSCAR are associated with and cause sleep disturbances and sleeplessness; Peyronie's disease and other penile deformities; fatigue and lethargy; male breasts (or gynecomastia); an increased risk of male breast cancer; and a form of high grade prostate cancer.

65. Despite the FDA requiring Merck to change its warnings for PROPECIA and PROSCAR, Merck immediately diluted those warning label changes by publicly denying in numerous major media outlets the causal relationship between PROPECIA and/or PROSCAR and the chronic side effects, described herein.

D. Merck's PROPECIA Marketing was Misleading and Encouraged Men to "Stick With" PROPECIA, Despite Suffering Harmful Side Effects

66. Merck received an FDA warning letter in March 2009, warning that Merck's aggressive online direct-to-consumer advertising campaign for PROPECIA was misleading by excluding risk information. In the online advertisement, Merck stated: "Finasteride Treatment: You May be able to keep some of the hair that you have….www.propecia.com." In response to this advertisement, the FDA found Merck's ad misleading:

Omission of Risk Information

These sponsored links make representations and/or suggestions about the efficacy of Januvia, Propecia, Singulair, and Emend, respectively, but fail to communicate any risk information. For promotional materials to be truthful and non-misleading, they must contain risk information in each part as necessary to qualify any claims made about the drug.

By omitting the most serious and frequently occurring risks associated with the drugs promoted in the links above, the sponsored links misleadingly suggest that Januvia, Propecia, Singulair, and Emend are safer than has been demonstrated. We note that these sponsored links contain a link to the products' websites. However, this is insufficient to mitigate the misleading omission of risk information from these promotional materials.

67. As part of its direct-to-consumer advertising campaign, Merck's website for PROPECIA, www.propecia.com, promoted the long-term use of PROPECIA through the "PROPECIA-Persistence Program", encouraging men to "stick with" using PROPECIA:

> PROPECIA can only work over the long term if you continue taking it. **If you stop taking PROPECIA, you will likely lose any hair you have gained within 12 months of stopping treatment**. (Emphasis added).

68. On Merck's PROPECIA website, www.propecia.com, Merck also offered the "12-Month Promise of PROPECIA"—a marketing and refund program to incentivize long term use of PROPECIA through its slogan "PROPECIA: Stick with it to see if it works for you."

69. On Merck's PROPECIA website, www.propecia.com, Merck's webpage for the "12-Month Promise of PROPECIA" states:

> Because hair loss may vary from one guy to the next, it makes sense that hair regrowth may vary among men. Some men notice a difference in as little as 3 months after starting treatment with PROPECIA, but most men have to use PROPECIA for at least 6 months before determining whether they have visible results. **That's why it's so important to stick with PROPECIA for at least 12 months to judge if it's working for you**. (Emphasis added).

70. Additionally the "12-Month Promise of PROPECIA" Program warns PROPECIA users:

> PROPECIA can only work over the long term if you continue taking it. **If you stop taking PROPECIA, you will likely lose any hair you have gained within 12 months of stopping treatment**. (Emphasis added).

71. The "12-Month Promise of PROPECIA" program offers incentives in the form of a full refund of 12-months of PROPECIA to those PROPECIA users that "stuck with" the hair loss drug for at least 12 months and did not receive the results they had anticipated, as judged by their prescriber. However, such refunds could only be valid if you "purchase your prescription(s) for a minimum of 12 consecutive months."

72. Merck, through the "PROPECIA-Persistence Program" and the "12-Month Promise of PROPECIA" Program, preyed upon the insecurities of men who were already concerned about their hair loss or potential for hair loss by threatening that users "will likely lose any hair [they] have gained" if they stop taking PROPECIA. These statements, particularly in the context of these Programs, were offered by Merck to encourage long term use of the drug.

73. Moreover, the "PROPECIA-Persistence Program" and the "12-Month Promise of PROPECIA" Program encouraged and incentivized men experiencing harmful side effects to continue taking the hair loss drug despite experiencing harmful side effects.

74. Moreover, the "PROPECIA-Persistence Program" and the "12-Month Promise of PROPECIA," particularly in light of PROPECIA's warning label advising potential users that sexual side effects "went away" in those men who discontinued use of PROPECIA and "disappeared in most men who continued taking PROPECIA," reflected an aggressive and intentional direct-to-consumer marketing and advertising campaign to convince potential users to try the cosmetic drug with no worry of chronic sexual side effects and to persist with long-term use even if the user happens to experience such serious side effects. This marketing and advertising campaign misled consumers and users as to the safety of PROPECIA.

E. Bosley's and MHR's PROPECIA Activities

75. For years, Bosley and MHR advertised, promoted, distributed, sold, supplied, and/or otherwise placed PROPECIA into the stream of commerce through their numerous office locations across the United States and Ohio, as well as through Bosley's and MHR's websites.

76. According to Bosley's website (www.bosley.com/bosley_and_mhr.php), effective June 1, 2010, Bosley and MHR "merged under the Bosley name."

77. Bosley continues to advertise, market, promote, distribute, sell, and/or place PROPECIA into the stream of commerce through its hair clinics in the U.S., including the state of Ohio, and online at its website, www.bosley.com.

SPECIFIC FACTUAL ALLEGATIONS

78. On or about February 2003, Plaintiff Richard Phelps was prescribed and supplied PROPECIA for male pattern hair loss through an MHR (now Bosley) office located at 425 Metro Place North, Suite 175, Dublin, Ohio 43017.

79. Plaintiff used PROPECIA as directed for male pattern hair loss for approximately 7 years.

80. Prior to using PROPECIA, Plaintiff did not suffer sexual dysfunction, including but not limited to, loss of libido; erectile dysfunction; decreased semen output; or orgasm and ejaculation disorders; nor did he suffer from fatigue; penile atrophy (shrinkage); or mental and emotional issues, such as anxiety and depression.

81. As a result of Plaintiff's use of PROPECIA for male pattern hair loss, Plaintiff has suffered significant and persistent and permanent injuries, including but not limited to, loss of libido; erectile dysfunction; decreased semen output; orgasm and ejaculation disorders; fatigue; penile atrophy (shrinkage); and mental and emotional issues, such as anxiety and depression.

82. Plaintiff will incurred medical, hospital, rehabilitative, and/or pharmaceutical expenses for the rest of his life.

83. As a direct and proximate cause of Defendants' conduct and Plaintiff's use of PROPECIA for male pattern hair loss, Plaintiff sustained persistent and permanent injury and impairment, lives in a constant state of fear and anxiety that his condition will worsen, and is unsure whether his injuries will ever resolve.

84. Also, as a direct and proximate cause of Defendants' conduct and Plaintiff's use of PROPECIA for male pattern hair loss, Plaintiff Bonnie Phelps has suffered damages due to the loss of her rights of consortium, lives in a constant state of fear and anxiety that her husband's condition will worsen, and is unsure whether his injuries will ever resolve.

COUNT I
PRODUCT LIABILITY—DEFECTIVE IN DESIGN OR FORMULATION
O.RC. § 2307.75
(As to Defendants Merck)

85. Plaintiffs incorporate by reference all preceding paragraphs in this Complaint as if fully set forth here and further allege as follows:

86. At all times material to the allegations in this Complaint, Defendants were engaged in the business of designing, testing, manufacturing, labeling, marketing, promoting, advertising, distributing, selling, and/or placing into the stream of commerce their product, PROPECIA, and did in fact sell and/or place into the stream of commerce their product, PROPECIA.

87. PROPECIA as designed, manufactured, marketed and sold by Defendants reached Plaintiff without substantial change in its condition and was used by Plaintiff in a manner reasonably foreseeable, intended, recommended, promoted, and/or marketed by Defendants.

88. PROPECIA was defective in design and formulation and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff. PROPECIA was dangerous beyond the reasonable expectation of the ordinary user/consumer, such as Plaintiff, because of its risks of chronic side effects, described herein, when used as intended and/or in a manner reasonably foreseeable. At no time did Plaintiff have reason to believe that PROPECIA was in a condition not suitable for its proper and intended use to address male pattern hair loss.

89. PROPECIA was defective in design and formulation in that Defendants failed to adequately warn and/or instruct PROPECIA users, like Plaintiff, and physicians, including Plaintiff's physicians, of the unreasonably unsafe aspects of PROPECIA, particularly the risk of chronic side effects, described herein.

90. Moreover, PROPECIA was defective in design and formulation in that PROPECIA's risks outweighed the benefits of its design. Particularly, because male pattern hair loss is neither an illness nor a disease, but, rather, a naturally occurring normal male phenomenon, the risk of chronic side effects described herein outweighs the benefit of potential cosmetic improvement in maintaining one's hair.

91. Plaintiff used and was exposed to PROPECIA in the manner intended and/or reasonably foreseeable by Defendants.

92. Defendants had a duty to not expose users and consumers of its product, such as Plaintiff, to unreasonable risks and dangers associated with PROPECIA.

93. Defendants knew, had reason to know, and/or should have known that their product would be used without inspection for defects, and by placing their drug on the market, represented that PROPECIA was safe when used as intended and/or in a reasonably foreseeable manner.

94. Defendants knew, had reason to know, and/or should have known, that PROPECIA would be used without inspection for defects; that any such inspection would not have revealed the underlying danger contained in Defendants' product; and that such exposure to Defendants' product could cause severe injury. Although these facts were known to or readily ascertainable by Defendants, Plaintiff and Plaintiff's physicians could not know nor contemplate the dangers of using PROPECIA in the manner intended and/or reasonably foreseeable.

95. Defendants' product contained latent characteristics and/or design defects at the time of manufacture and Plaintiff's exposure. Defendants knew, had reason to know, and/or should have known, that Plaintiff's exposure to Defendants' product was harmful and could cause significant and chronic injuries, as described herein.

96. PROPECIA was defective in that Defendants insufficiently tested and studied their product and PROPECIA caused harmful chronic side effects that outweighed any potential benefit for cosmetic improvement.

97. PROPECIA, as manufactured by Defendants, was defective due to inadequate post-marketing warnings. After Defendants knew, had reason to know, and/or should have known of the risk of injuries from PROPECIA use and acquired knowledge and information confirming the defective and dangerous nature of PROPECIA, Defendants failed to provide adequate warnings to the medical community, including Plaintiff's physicians, and consumers, like Plaintiff, to whom Defendants were directly marketing and advertising. In fact, Defendants continued to affirmatively promote PROPECIA as safe for addressing male pattern hair loss to this very day, publicly denying the chronic side effects described herein.

98. Moreover, even when Defendants were ordered by the FDA to issue a label change suggesting the relationship between PROPECIA and chronic side effects, Defendants immediately

diluted those changes by publicly denying that PROPECIA caused any of the harmful chronic side effects described herein.

99. As a result of Defendants' defective design of PROPECIA, including the lack of appropriate warnings, Plaintiff was prescribed and used the drug.

100. As a result of Plaintiff's exposure to Defendants' product, PROPECIA caused injuries and damages. Particularly, Plaintiff has suffered significant and persistent and/or permanent injuries, including but not limited to, loss of libido; erectile dysfunction; decreased semen output; orgasm and ejaculation disorders; fatigue; penile atrophy (shrinkage); and mental and emotional issues, such as anxiety and depression.

101. As a direct and proximate cause of Defendants' defective design of PROPECIA, Plaintiff suffered the damages and injuries described herein, including severe and permanent injuries; severe emotional distress; pain and suffering; and other damages to be proved at trial.

COUNT II
PRODUCT LIABILITY—DEFECTIVE DUE TO INADEQUATE WARNING OR INSTRUCTION O.R.C. § 2307.76
(As to Defendants Merck)

102. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth here and further allege as follows:

103. At all times material to the allegations in this Complaint, Defendants were engaged in the business of designing, testing, manufacturing, labeling, marketing, promoting, advertising, distributing, selling, and/or placing into the stream of commerce their product, PROPECIA, and did in fact sell and/or place into the stream of commerce their product, PROPECIA.

104. Plaintiff used and was exposed to PROPECIA in the manner intended and/or reasonably foreseeably by Defendants during which time Defendants' product caused the injuries and damages set forth herein.

105. By placing PROPECIA on the market, Defendants represented that their product was safe for its intended and/or reasonably foreseeable use and purpose.

106. Defendants knew, had reason to know, and/or should have known that PROPECIA would be used without inspection for defects; that any such inspection would not have revealed the underlying danger contained in Defendants' product; and that such exposure to Defendants' product could cause severe injury. Although these facts were known to or readily ascertainable by Defendants, Plaintiff could not know nor contemplate the dangers of using PROPECIA in the manner intended and/or reasonably foreseeable, making PROPECIA inherently and unreasonably dangerous.

107. When used, PROPECIA failed to perform as safely as a consumer, like Plaintiff, would have expected and the risks of Defendants' product outweighed its benefits. Particularly, because male pattern hair loss is neither an illness nor a disease, but, rather, a naturally occurring normal male phenomenon, the risk of chronic side effects described herein outweighs the benefit of potential cosmetic improvement in maintaining one's hair.

108. Defendants have a duty to provide adequate warnings and instructions for PROPECIA of the dangers and risks caused and/or associated with using PROPECIA for male pattern hair loss.

109. PROPECIA was defective and unreasonably dangerous when it left the possession of Defendants in that PROPECIA contained insufficient and inadequate warnings to alert consumers, including Plaintiff, and prescribing physicians, including Plaintiff's physicians, of the harmful risk of serious chronic side effects, as described herein.

110. Defendants have a continuing duty to warn Plaintiff and his prescribing physicians of the dangers and risks caused or associated with PROPECIA after the marketing of Defendants' product.

111. PROPECIA, as manufactured by Defendants, was defective due to inadequate post-marketing warnings. After Defendants knew, had reason to know, and/or should have known of the risk of injuries from PROPECIA use and acquired knowledge and information confirming the defective and dangerous nature of PROPECIA, Defendants failed to provide adequate warnings to the medical community, including Plaintiff's physicians, and consumers, like Plaintiff, to whom Defendants were directly marketing and advertising. In fact, Defendants continued to affirmatively market and promote PROPECIA as safe for addressing male pattern hair loss to both the medical community and directly to consumers to this very day, publicly denying the chronic side effects described herein.

112. Defendants' warnings for PROPECIA were also inadequate in that Defendants' failed to warn U.S. users and consumers, like Plaintiff, and U.S. physicians, including Plaintiff's physicians, that PROPECIA's sexual side effects were chronic and would not "[go] away in men who stopped taking PROPECIA," despite providing warnings and instructions to foreign users and consumers of PROPECIA that certain sexual side effects could be persistent and chronic.

113. Defendants' warnings regarding the risks and dangers for PROPECIA failed to properly and adequately warn of the increased risk of serious injury associated with and/or caused by PROPECIA.

114. Neither Plaintiff, nor Plaintiff's physicians knew, nor could they have learned through the exercise of reasonable care, the risk of serious injury associated with and/or caused by PROPECIA.

115. If adequate warnings had been provided, Plaintiff's physicians would not have prescribed nor would Plaintiff have purchased, used, and been injured by PROPECIA.

116. Defendants breached their duty by failing to adequately warn users and consumers, like Plaintiff, and physicians, like Plaintiff's physicians, of the risk of serious and chronic side effects caused from the use of PROPECIA, as described herein.

117. As a result of Defendants' failure to adequately warn of the risks caused by PROPECIA and Plaintiff's exposure to Defendants' product, PROPECIA caused injuries and damages. Particularly, Plaintiff has suffered significant and persistent and/or permanent injuries, including but not limited to, loss of libido; erectile dysfunction; decreased semen output; orgasm and ejaculation disorders; fatigue; penile atrophy (shrinkage); and mental and emotional issues, such as anxiety and depression.

118. As a direct and proximate result of Defendants' conduct alleged herein, Plaintiff was caused to suffer significant and permanent injuries and damages, as described herein, severe emotional distress; pain and suffering; and other damages to be proved at trial.

COUNT III
PRODUCT LIABILITY—DEFECTIVE DUE TO NONCONFORMANCE WITH MANUFACTURERS' REPRESENTATIONS O.R.C. § 2307.77
(As to Defendants Merck)

119. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth here and further allege as follows:

120. At all times material to the allegations in this Complaint, Defendants were engaged in the business of designing, testing, manufacturing, labeling, marketing, promoting, advertising, distributing, selling, and/or otherwise placing into the stream of commerce their product, PROPECIA, and did in fact sell and/or otherwise place into the stream of commerce PROPECIA.

121. PROPECIA was designed, tested, manufactured, labeled, marketed, promoted, advertised, distributed, sold, and/or placed into the stream of commerce by Defendants and in fact used by Plaintiff.

122. At the time Defendants designed, manufactured, labeled, marketed, promoted, advertised, distributed, sold, and/or placed into the stream of commerce PROPECIA, Defendants' product was expected to, and did, reach Plaintiff in a condition without substantial change from when it was within the possession of Defendants.

123. Defendants had a duty to not expose Plaintiff to risks and dangers associated with their product, PROPECIA.

124. When used, PROPECIA failed to perform as safely as Plaintiff and Plaintiff's physicians expected and as safely as represented by Defendants.

125. Plaintiff's physicians prescribed and Plaintiff used and was exposed to PROPECIA in the manner intended by and/or reasonably foreseeable to Defendants.

126. Defendants' product contained latent characteristics and/or design defects at the time of manufacture and Plaintiff's exposure and Defendants knew, had reason to know, and/or should have known that Plaintiff's exposure to PROPECIA was harmful and could cause chronic side effects and significant permanent injuries, as set forth herein.

127. Defendants knew, had reason to know, and/or should have known that PROPECIA would be used without inspection for defects; that any such inspection would not have revealed the underlying danger contained in Defendants' product; and that such exposure to Defendants' product could cause severe injury. Although these facts were known to or readily ascertainable by Defendants, Plaintiff and Plaintiff's physicians could not know nor contemplate the dangers of using PROPECIA in the manner intended and/or reasonably foreseeable.

128. Plaintiff, unaware of the defective and unreasonably dangerous condition of PROPECIA at the time when such product was being used by Plaintiff, was exposed to the inherent risks and dangers of Defendants' product, making PROPECIA unsafe for its intended and/or reasonably foreseeable use.

129. When PROPECIA left Defendants' control, PROPECIA was not reasonably safe because PROPECIA failed to conform to Defendants' representations made through their labeling, advertising, marketing, promoting, publications, and/or regulatory submissions as to the safety of PROPECIA, including the following particulars:

a. Defendants misrepresented that certain sexual side effects caused and/or associated with the use of PROPECIA were only temporary and would "go away" upon discontinuation of the drug when Defendants knew, had reason to know, and/or should have known that these sexual side effects could be chronic, despite discontinuation of PROPECIA;

b. Defendants misrepresented that certain sexual side effects caused and/or associated with the use of PROPECIA for male pattern hair loss "disappeared" in most men who continued using Defendants' product when Defendants knew, had reason to know, and/or should have known that these side effects persist and could be chronic;

c. Defendants misrepresented that users, like Plaintiff, "stick with" the use of PROPECIA for male pattern hair loss despite users, like Plaintiff, suffering serious side effects which Defendants knew, had reason to know, and/or should have known could persist and be chronic;

d. Defendants misrepresented that PROPECIA had been adequately tested and found to be safe for male pattern hair loss;

e. Defendant omitted and/or concealed safety information regarding risks of serious injury associated with using PROPECIA; and

f. Defendants misrepresented that certain sexual side effects "went away" in men who discontinued use of PROPECIA and omitted and/or concealed material information about the chronic nature of PROPECIA's sexual side effects from U.S. users and consumers, like Plaintiff, and U.S. physicians, including Plaintiff's physicians, despite providing warnings and instructions to foreign users and consumers of PROPECIA that certain sexual side effects could be persistent and chronic.

130. Defendants' representations as to the safety of PROPECIA for male pattern hair loss were material facts concerning their product and were justifiably relied upon by Plaintiff and Plaintiff's physicians in that Plaintiff's physicians prescribed PROPECIA and Plaintiff purchased and used PROPECIA.

131. Plaintiff's physicians would not have prescribed nor would Plaintiff have purchased and used PROPECIA if they knew the risk of chronic side effects caused and/or associated with using PROPECIA for male pattern hair loss, including, particularly, the risk of chronic sexual dysfunction after discontinuation of the product, despite Defendants' representations to the contrary.

132. Defendants are subject to liability for such representations and the failure to conform to the representations even if Defendants did not act fraudulently, recklessly, or negligently in making such representations. O.R.C. § 2307.77.

133. As a result of Plaintiff's and Plaintiff's physicians' reliance on Defendants' representations, PROPECIA caused injuries and damages. Particularly, Plaintiff has suffered significant and persistent and/or permanent injuries, including but not limited to, loss of libido; erectile dysfunction; decreased semen output; orgasm and ejaculation disorders; fatigue; penile atrophy (shrinkage); and mental and emotional issues, such as anxiety and depression.

134. As a direct and proximate consequence of Plaintiff's and Plaintiff's physicians' justifiable reliance on Defendants' representations regarding PROPECIA, Plaintiff sustained injuries and damages including severe and permanent injuries; severe emotional distress; pain and suffering; and other damages to be proved at trial.

COUNT IV
SUPPLIER LIABILITY
O.R.C. § 2307.78
(As to Defendants MHR & Bosley)

135. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows:

136. Defendants Bosley and MHR are suppliers of PROPECIA that is the subject of this Complaint as defined under O.R.C. § 2307.71 in that Bosley and MHR are not the manufacturers of PROPECIA but sold, distributed, and/or otherwise participated in the placement of PROPECIA in the stream of commerce.

137. Defendants are liable as suppliers under O.R.C. § 2307.78 as Defendants were negligent in their distribution, sale, supply, and/or participation in the placement of PROPECIA in the stream of commerce and that negligence was a direct and proximate cause of harm for which the Plaintiff seeks to recover compensatory damages.

138. Specifically, in violation of O.R.C. § 2307.78(A)(1), Defendants were negligent in breaching their duties and in failing to exercise reasonable care, as follows:

a. In failing to provide adequate warnings or instructions concerning the harmful side effects associated with and/or caused by PROPECIA where a reasonably prudent supplier should have learned about the dangers and risks connected with PROPECIA;

b. In advertising, promoting, and/or marketing PROPECIA to Plaintiff and customers like Plaintiff without providing adequate warnings and/or instructions regarding the risks associated with and/or caused by PROPECIA; and

c. In failing to take reasonable precautions and/or exercising reasonable care in distributing, selling, supplying, and/or otherwise participating in the placing of PROPECIA into the stream of commerce to Plaintiff and consumers like Plaintiff.

139. Further, in violation of O.R.C. § 2307.78(A)(2), PROPECIA failed to conform, when it left the control of Defendants, as the suppliers of PROPECIA, to representations made by Defendants—namely that PROPECIA was safe to address male pattern hair loss.

140. Under O.R.C. § 2307.78(A)(2), Defendants are subject to liability for such representations concerning PROPECIA and the failure to conform to them even if Defendants did not act fraudulently, recklessly, or negligently in making the representation.

141. As a result of Plaintiff's reliance on Defendants' representations, PROPECIA caused injuries and damages. Particularly, Plaintiff has suffered significant and persistent and/or permanent injuries, including but not limited to, loss of libido; erectile dysfunction; decreased semen output; orgasm and ejaculation disorders; fatigue; penile atrophy (shrinkage); and mental and emotional issues, such as anxiety and depression.

142. As a direct and proximate consequence of Plaintiff's justifiable reliance on Defendants' representations regarding PROPECIA, Plaintiff sustained injuries and damages including severe and permanent injuries; severe emotional distress; pain and suffering; and other damages to be proved at trial.

COUNT V
NEGLIGENCE
(As to Defendants Merck)

143. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth here and further allege as follows:

144. At all times material to the allegations in this Complaint, Defendants were engaged in the business of designing, testing, manufacturing, labeling, marketing, promoting, distributing, selling, and/or otherwise placing into the stream of commerce their product, PROPECIA, and did in fact sell and/or otherwise place into the stream of commerce PROPECIA.

145. Defendants owed Plaintiff a duty to exercise reasonable care when designing, formulating, testing, manufacturing, labeling, marketing, advertising, promoting, distributing, selling, and/or placing into the stream of commerce Defendants' product, PROPECIA.

146. Defendants breached their duty by failing to exercise ordinary care in designing, formulating, testing, manufacturing, labeling, marketing, advertising, promoting, distributing, selling, and/or placing into the stream of commerce Defendants' product, PROPECIA.

147. Defendants failed to exercise reasonable care under the circumstances and therefore breached their duty in numerous ways, including the following:

a. failing to use reasonable care in accompanying PROPECIA with adequate and proper warnings and instructions to users and consumers, like Plaintiff, and physicians, like Plaintiff's physicians, regarding the risks and dangers of using

PROPECIA for male pattern hair loss, including the risks of serious chronic side effects described herein, which Defendants knew, had reason to know, and/or should have known were caused by PROPECIA;

b. failing to use reasonable care in the design, development, and preparation of PROPECIA to prevent the risk of injuries described herein;

c. failing to use reasonable care in the manufacture, inspection, and labeling of PROPECIA to prevent the risk of injuries, detailed herein;

d. failing to properly, adequately, and/or thoroughly research and test PROPECIA before releasing the drug to the market;

e. failing to properly, adequately, and/or thoroughly study, analyze, and/or interpret the information resulting from the pre-marketing tests of PROPECIA;

f. failing to adequately disclose and/or report the results of any pre-marketing testing and post-marketing surveillance and testing of PROPECIA which indicated serious risks associated with its use to users and consumers, like Plaintiff; physicians including Plaintiff's physicians; the general public; and/or the FDA;

g. failing to conduct adequate analysis of adverse event reports;

h. failing to use reasonable care when advertising PROPECIA to prevent the risk of injuries, described herein;

i. failing to use reasonable care in the promotion of PROPECIA to prevent the risk of injuries, described herein;

j. failing to use reasonable care in the marketing of PROPECIA to prevent the risk of injuries, described herein;

k. failing to use reasonable care in the sale of PROPECIA to prevent the risk of injuries, described herein;

l. misrepresenting to all users, including Plaintiff, and physicians, including Plaintiff's physicians, that certain sexual side effects experienced while using PROPECIA for male pattern hair loss were temporary and would "go away" upon discontinuation of the drug;

m. misrepresenting to all users, including Plaintiff, and physicians, including Plaintiff's physicians, that certain sexual side effects caused and/or associated with the use of PROPECIA for male pattern hair loss "disappeared" in most men who continued using PROPECIA, despite the sexual side effects persisting and being chronic in nature;

n. failing to provide similar warnings to U.S. users and consumers of PROPECIA, like Plaintiff, and U.S. physicians, including Plaintiff's physicians, that Defendants provided to foreign users and consumers—namely, that certain sexual side effects may not "go away" upon discontinuation of use of PROPECIA and in fact may be persistent and chronic;

o. failing to conduct adequate post-marketing surveillance and exposure studies, including post-marketing testing and research, to determine the safety of using PROPECIA when Defendants knew, had reason to know, or should have known, that post-marketing surveillance and studies were necessary to determine the relative risk of PROPECIA for causing serious injury in the absence of clinical trials; the need to revise the warning labeling to reflect any risk of serious injury; and/or the need to withdraw the drug from the market;

p. failing to provide adequate post-marketing warnings as to the risk of serious adverse side effects from using PROPECIA for male pattern hair loss after Defendants knew, had reason to know, or should have known, about the risk connected with their product;

q. continuing to manufacture, market, advertise, and distribute PROPECIA after Defendants knew, had reason to know, or should have known, of the risks of serious injury associated with using the drug;

r. failing to provide adequate and accurate training and information to the sales representatives who sold PROPECIA;

s. failing to provide adequate and accurate training and information to healthcare providers for the appropriate use of PROPECIA;

t. failing to give patients and healthcare providers adequate information to weigh the risks of serious injury in relation to benefits of the drug; and

u. being otherwise reckless, careless and/or negligent.

148. As a result of Defendants' negligent conduct, Plaintiff did in fact suffer injuries and damages. Particularly, Plaintiff has suffered significant and persistent and/or permanent injuries, including but not limited to, loss of libido; erectile dysfunction; impotence; decreased semen output; and orgasm disorders; and mental and emotional issues, such as anxiety, depression, and cognitive impairment.

149. As a direct and proximate result of Defendants' negligence, described herein, Plaintiff sustained injuries and damages, including severe and permanent injuries; pain and suffering; severe emotional distress; and other damages to be proved at trial.

COUNT VI
NEGLIGENCE
(As to Defendants MHR & Bosley)

150. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth here and further allege as follows:

151. At all times material to the allegations in this Complaint, Defendants were engaged in the business of marketing, promoting, advertising, distributing, supplying, selling, and/or otherwise placing into the stream of commerce PROPECIA and did in fact sell, supply, and/or otherwise place into the stream of commerce PROPECIA.

152. Defendants owed Plaintiff a duty to exercise reasonable care when marketing, advertising, promoting, distributing, selling, supplying, selling, and/or placing into the stream of commerce PROPECIA.

153. Defendants breached their duty by failing to exercise reasonable care in marketing, advertising, promoting, distributing, selling, supplying, and/or placing into the stream of commerce PROPECIA, as described herein.

154. As a result of Defendants' failure to use reasonable care, Plaintiff was directly and proximately caused to suffer injuries and damages. Particularly, Plaintiff has suffered significant and persistent and/or permanent injuries, including but not limited to, loss of libido; erectile dysfunction; decreased semen output; orgasm and ejaculation disorders; fatigue; penile atrophy (shrinkage); and mental and emotional issues, such as anxiety and depression.

155. As a direct and proximate result of Defendants' negligence, described herein, Plaintiff sustained injuries and damages, including severe and permanent injuries; pain and suffering; severe emotional distress; and other damages to be proved at trial.

COUNT VII
BREACH OF EXPRESS WARRANTIES
O.R.C. § 1302.26
(As to Defendants Merck)

156. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth here and further allege as follows:

157. Defendants designed, tested, labeled, manufactured, marketed, promoted, advertised, distributed, sold, and/or placed into the stream of commerce PROPECIA.

158. At the time Defendants designed, tested, labeled, manufactured, marketed, promoted, advertised, distributed, sold, and/or otherwise placed PROPECIA into the stream of commerce, Defendants knew, had reason to know, and/or should have known the intended and/or reasonably foreseeable use for PROPECIA and expressly warranted that PROPECIA was safe for such use.

159. Defendants expressly warranted to consumers, like Plaintiff; the medical community, including Plaintiff's physicians; and the general public by affirmations of fact, descriptions, and/or promises that PROPECIA was safe; efficacious; fit for its intended purposes; of merchantable quality; and did not produce any undisclosed harmful side effects.

160. Under O.R.C. § 1302.26, Defendants breached their express warranties with respect to PROPECIA, including the following particulars:

a. Defendants warranted that certain sexual side effects experienced while using PROPECIA were temporary and would "go away" upon discontinuation of use of the drug, and withheld and concealed information about the risks of permanent injury associated with using PROPECIA, despite discontinuing use of the drug;

b. Defendants warranted that certain sexual side effects caused and/or associated with the use of PROPECIA for male pattern hair loss "disappeared" in most men

who continued using PROPECIA, despite having reason to know that these sexual side effects persisted and were chronic in nature;

c. Defendants warranted to U.S. users and consumers of PROPECIA, like Plaintiff, and U.S. physicians, including Plaintiff's physicians, that certain sexual side effects caused and/or associated with the use of PROPECIA for male pattern hair loss "went away" in men who discontinued use of PROPECIA, despite providing warnings and instructions to foreign users and consumers of PROPECIA that certain sexual side effects could be persistent and chronic; and

d. Defendants warranted through their labeling, advertising, promoting, marketing, publications, and/or regulatory submissions that PROPECIA was safe and withheld and concealed information about the substantial risks of serious injury associated with using PROPECIA.

161. These affirmations of fact, descriptions, and/or promises made by Defendants became part of the basis of the bargain for Plaintiff and Plaintiff's physicians in determining whether to prescribe, purchase, and/or use PROPECIA for male pattern hair loss.

162. PROPECIA did not conform to Defendants' express warranties because the drug was not safe or well-tolerated since PROPECIA has numerous chronic sexual side effects and numerous undisclosed and unwarned of chronic side effects which cause severe and/or permanent injuries, as described herein.

163. At all relevant times, PROPECIA did not perform as safely as an ordinary consumer would expect when used as intended and/or in a reasonably foreseeable manner.

164. Plaintiff ingested PROPECIA in reliance upon the express warranties given to Plaintiff, Plaintiff's physicians, consumers, the medical community, and the general public.

165. PROPECIA did not conform to the affirmations of fact and/or promises and descriptions made by Defendants, particularly those made by Defendants in that any sexual dysfunction experienced by Plaintiff did not "[go] away" once use of PROPECIA was discontinued.

166. As a result of Plaintiff's reliance upon Defendants' express warranties, Plaintiff has suffered significant and persistent and/or permanent injuries, including but not limited to, loss of libido; erectile dysfunction; decreased semen output; orgasm and ejaculation disorders; fatigue; penile atrophy (shrinkage); and mental and emotional issues, such as anxiety and depression.

167. As a direct and proximate consequence of Defendants' breach of their express warranties with respect to PROPECIA, Plaintiff sustained injuries and damages alleged herein, including severe and permanent injuries; severe emotional distress; pain and suffering; and other damages to be proved at trial.

COUNT VIII
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
O.R.C. § 1302.27
(As to Defendants Merck)

168. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth here and further allege as follows:

169. Defendants designed, tested, manufactured, labeled, marketed, advertised, promoted, distributed, sold, and/or otherwise placed into the stream of commerce PROPECIA.

170. At the time Defendants designed, manufactured, labeled, marketed, advertised, promoted, distributed, sold, and/or otherwise placed into the stream of commerce PROPECIA, Defendants knew, had reason to know, and/or should have known the intended and/or reasonably foreseeable use for PROPECIA and impliedly warranted PROPECIA to be of merchantable quality and safe for such use.

171. At all relevant times, PROPECIA was used by Plaintiff in the manner that was intended and/or reasonably foreseeable by Defendants.

172. Defendants impliedly warranted PROPECIA to be of merchantable quality, safe, and fit for the intended and/or reasonably foreseeable use. Defendants warranted that PROPECIA would pass without objection under the contract description; was fit for its ordinary purpose for which their product was used; was adequately contained, packaged, and labeled; and conformed to promises and affirmations of fact made on the container and/or label.

173. Defendants were aware that consumers, including Plaintiff, would use PROPECIA for male pattern hair loss and, thus, Plaintiff was a foreseeable user of PROPECIA. Plaintiff in fact used PROPECIA in a manner intended and/or reasonably foreseeable by Defendants.

174. PROPECIA was expected to reach and did in fact reach Plaintiff without substantial change in the condition in which it was manufactured and sold by Defendants.

175. Defendants breached various implied warranties, in violation of O.R.C. § 1302.27, with respect to PROPECIA through their labeling, advertising, marketing, promoting, publications, and/or regulatory submissions in that PROPECIA:

a. was not of merchantable quality, safe, and fit for its intended and/or reasonably foreseeable use;

b. would not pass without objection in the trade;

c. was not fit for its ordinary purpose;

d. was not adequately contained, packaged, and labeled;

e. did not conform to promises and affirmations of fact made on its container and/or label;

f. was not safe for its intended and/or reasonably foreseeable use since Defendants knew, had reason to know, and/or should have known that PROPECIA posed a substantial risk of serious injury for users, like Plaintiff;

g. was not safe for its intended and/or reasonably foreseeable use, since Defendants withheld, concealed, and/or omitted information that PROPECIA posed a substantial risk of serious injury for users, like Plaintiff; and

h. was unreasonably dangerous, defective, and unfit for the intended, recommended, promoted, marketed, and/or reasonably foreseeable purpose.

176. In reliance upon Defendants' implied warranties, Plaintiff's physicians prescribed and Plaintiff purchased and used PROPECIA in a manner intended, recommended, promoted, marketed, and/or reasonably foreseeable by Defendants.

177. As a result of Plaintiff's and Plaintiff's physicians' reliance on Defendants' implied warranties, Plaintiff has suffered significant and persistent and/or permanent injuries, including but not limited to, loss of libido; erectile dysfunction; decreased semen output; orgasm and ejaculation disorders; fatigue; penile atrophy (shrinkage); and mental and emotional issues, such as anxiety and depression.

178. As a direct and proximate result of Defendants' breach of their implied warranties, Plaintiff sustained injuries and damages alleged herein, including severe and permanent injuries; severe emotional distress; pain and suffering; and other damages to be proved at trial.

COUNT IX
FRAUD
(As to Defendants Merck)

179. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth here and further allege as follows:

180. At all times material to the allegations in this Complaint, Defendants were engaged in the business of designing, testing, manufacturing, labeling, marketing, promoting, advertising, distributing, selling, and/or placing into the stream of commerce their product, PROPECIA, and did in fact sell and/or place into the stream of commerce their product, PROPECIA.

181. Defendants had the duty to provide truthful, adequate, and accurate representations regarding the safety of PROPECIA and to disclose the risks associated with PROPECIA that Defendants knew or had reason to know of to users and consumers, like Plaintiff; the medical community, including Plaintiff's physicians; the general public; and the FDA, as the designers, testers, manufacturers, labelers, marketers, promoters, advertisers, distributors, and/or sellers of PROPECIA.

182. Moreover, Defendants had a duty to ascertain whether their representations were truthful, adequate, and accurate and were in a position to determine the truthfulness, adequacy, and accuracy of their representations.

183. PROPECIA's benefits outweighed its risks. In fact, Defendants knew or had reason to know and fraudulently concealed that PROPECIA is dangerous to users and that the benefits of its use for cosmetic improvement are far outweighed by the risk of chronic side effects for its users, like Plaintiff, as described herein.

184. At all relevant times, PROPECIA was used by Plaintiff in the manner that was intended and/or reasonably foreseeable by Defendants and Defendants expressly and/or impliedly warranted their product was of merchantable quality and safe and fit for such use.

185. Defendants had sole access to material facts concerning the dangers and unreasonable risks of PROPECIA. Defendants were in a position to provide superior knowledge and expertise regarding PROPECIA; specific knowledge regarding the risks and dangers of their product; and

absolute control and discretion regarding the dissemination of promotional and marketing information and materials, as well as safety information, about their product, all of which give rise to the affirmative duty to meaningfully disclose and provide all material information about the risks and harms associated with using PROPECIA.

186. At all times relevant to herein, Defendants failed to warn consumers that the use of PROPECIA for male pattern hair loss could result in chronic sexual dysfunction as well as other chronic side effects described herein, despite receiving adverse reports by PROPECIA users and prescribing doctors beginning in the late 1990's.

187. Defendants made fraudulent misrepresentations which misstated, misrepresented, and/or suppressed material facts relating to the risks, dangers, safety, utility, and benefits of using PROPECIA for male pattern hair loss to users and consumers, like Plaintiff; the general public; the FDA; and the medical community, including Plaintiff's physicians.

188. Defendants fraudulently concealed material facts relating to the risks, dangers, safety, utility, and benefits of using PROPECIA for male pattern hair loss from users and consumers, like Plaintiff; the general public; the FDA; and the medical community, including Plaintiff's physicians.

189. By misrepresenting and failing to disclose important safety and injury information and suppressing material facts about PROPECIA to users and consumers, like Plaintiff; Plaintiff's physicians; the medical community; the general public; and the FDA, Defendants further led Plaintiff and Plaintiff's physicians to rely upon the safety of PROPECIA.

190. Defendants' fraudulent and intentional misrepresentations, omissions, and/or concealments misstated, misrepresented, and/or suppressed material facts through their labeling, advertising, marketing, promoting, publications, and/or regulatory submissions relating to the risks

and dangers of using PROPECIA for addressing male pattern hair loss, including the following particulars:

a. Defendants intentionally and fraudulently misrepresented that certain sexual side effects caused and/or associated with the use of PROPECIA were only temporary and would "go away" upon discontinuation of the drug when Defendants knew, had reason to know, and/or should have known that these sexual side effects could persist and be chronic, despite discontinuation of PROPECIA;

b. Defendants intentionally and fraudulently misrepresented that certain sexual side effects caused and/or associated with the use of PROPECIA for male pattern hair loss "disappeared" in most men who continued using Defendants' product when Defendants knew, had reason to know, and/or should have known that these side effects persist and could be chronic;

c. Defendants intentionally and fraudulently misrepresented to users, like Plaintiff, to "stick with" the use of PROPECIA for male pattern hair loss despite users, like Plaintiff, suffering serious side effects when Defendants knew, had reason to know, and/or should have known that these side effects persist and could be chronic;

d. Defendants intentionally and fraudulently misrepresented that PROPECIA had been adequately tested and found to be safe for male pattern hair loss;

e. Defendants fraudulently omitted and/or concealed information about the substantial risks of serious injury associated with using PROPECIA;

f. Defendants intentionally and fraudulently misrepresented that certain sexual side effects "went away" in men who discontinued use of PROPECIA and omitted or concealed material information about the chronic nature of PROPECIA's sexual side effects from U.S. users and consumers, like Plaintiff, and U.S. physicians, including Plaintiff's physicians, despite providing warnings and instructions to foreign users and consumers of PROPECIA that certain sexual side effects could be persistent and chronic.

191. Defendants knew or had reason to know that these misrepresentations, omissions, and/or concealments of adverse material information were false and that PROPECIA had defects in its design and was unreasonably dangerous.

192. Defendants willfully, wantonly, and recklessly disregarded their obligation to provide truthful and forthright representations regarding the safety and risk of PROPECIA to users and consumers, including Plaintiff; the medical community, including Plaintiff's physicians; the general public; and the FDA.

193. Further, Defendants did not have adequate proof upon which to base such representations as described herein, and in fact, given Defendants' specific knowledge about the design and formulation of PROPECIA and the reported adverse events associated with their drug, Defendants knew or had reason to know that these representations, omissions, and/or concealments were not forthright and were false and fraudulent. Particularly, Defendants knew or had reason to know that PROPECIA was unreasonably dangerous; causes serious harmful risk as described herein; and that certain sexual side effects did not "go away" with discontinuation of Defendants' drug.

194. Defendants made such fraudulent and/or intentional misrepresentations, omissions, and/or concealments with the intent or purpose that Plaintiff and Plaintiff's physicians would

reasonably and/or justifiably rely upon such misrepresentations, omissions, and/or concealments, leading to Plaintiff's physician prescribing PROPECIA and Plaintiff purchasing and using PROPECIA. Defendants' misrepresentations, omissions, and/or concealments were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to increase and maximize the sales of PROPECIA.

195. In fact, Plaintiff and Plaintiff's physicians did not know these representations, omissions, and/or concealments were fraudulent and reasonably and/or justifiably relied upon and were induced by Defendants' misrepresentations, omissions, and/or concealments of the risks and dangers of permanent injury from PROPECIA to Plaintiff's detriment in that Plaintiff purchased and used PROPECIA.

196. Had Defendants not fraudulently misrepresented, omitted, and/or concealed such information, Plaintiff would not have ingested PROPECIA and suffered resulting harm.

197. Defendants knew that without truthful and accurate information and warnings regarding PROPECIA, Plaintiff and Plaintiff's physicians could not make an informed choice about the risks and benefits of using PROPECIA for male pattern hair loss

198. Moreover, Defendants continue to misrepresent, omit, and/or conceal the chronic nature of the side effects of PROPECIA by denying and downplaying the causal relationship between the chronic side effects, described herein, and their product to this very day.

199. Further, even when Defendants were ordered by the FDA to issue a label change suggesting the relationship between PROPECIA and chronic side effects, Defendants immediately diluted those changes by publicly denying that PROPECIA caused any of the harmful chronic side effects described herein.

200. As a result of Defendants' intentional and fraudulent misrepresentations, omissions, and/or concealments, Plaintiff has suffered significant and persistent and/or permanent injuries, including but not limited to, loss of libido; erectile dysfunction; decreased semen output; orgasm and ejaculation disorders; fatigue; penile atrophy (shrinkage); and mental and emotional issues, such as anxiety and depression.

201. As a direct and proximate result of Defendants' intentional and fraudulent misrepresentations, omissions, and/or concealments upon which Plaintiff and Plaintiff's physicians reasonably relied, Plaintiff sustained injuries and damages alleged herein, including severe and permanent injuries; severe emotional distress; pain and suffering; and other damages to be proved at trial.

COUNT X
NEGLIGENT MISREPRESENTATION
(As to Defendants Merck)

202. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth here and further allege as follows:

203. At all times material to the allegations in this Complaint, Defendants were engaged in the business of designing, testing, manufacturing, labeling, marketing, promoting, advertising, distributing, selling, and/or placing into the stream of commerce their product, PROPECIA, and did in fact sell and/or place into the stream of commerce their product, PROPECIA.

204. At all relevant times, PROPECIA was used by Plaintiff in the manner that was intended and/or reasonably foreseeable by Defendants and Defendants expressly and/or impliedly warranted their product was of merchantable quality and safe and fit for such use.

205. Defendants owed Plaintiff a duty to exercise reasonable care when designing, testing, manufacturing, labeling, marketing, advertising, promoting, distributing, selling, and/or placing into the stream of commerce PROPECIA.

206. Defendants had the duty to provide truthful, adequate, and accurate representations regarding the safety of PROPECIA and to disclose the risks associated with PROPECIA that Defendants knew, had reason to know, and/or should have known of, to users and consumers, like Plaintiff; the medical community, including Plaintiff's physicians; the general public; and the FDA, as the designers, testers, manufacturers, labelers, marketers, promoters, advertisers, distributors, and/or sellers of PROPECIA.

207. Moreover, Defendants had a duty to ascertain whether their representations were truthful, adequate, and accurate and were in a position to determine the truthfulness, adequacy, and accuracy of their representations.

208. PROPECIA's benefits outweighed its risks. In fact, Defendants knew, had reason to know, and/or should have known and misrepresented that PROPECIA is safe for its users; that it does not cause chronic side effects, as described herein; and that the benefits of its use for cosmetic improvement outweigh the risk experiencing chronic side effects for Plaintiffs and users in general.

209. Defendants made negligent misrepresentations which misstated, misrepresented, and/or suppressed material facts relating to the risks and dangers of using PROPECIA for male pattern hair loss.

210. Defendants' negligent misrepresentations were made under circumstances in which Defendants had reason to know, should have known, and/or were in the position to know that they were not accurate and truthful.

211. Defendants had sole access to material facts concerning the dangers and unreasonable risks of PROPECIA. Defendants were in a position which provided them with superior knowledge and expertise regarding PROPECIA; specific knowledge regarding the risks and dangers of their product; and absolute control and discretion regarding the dissemination of promotional and marketing information and materials, as well as safety and risk information, about their product, all of which give rise to the affirmative duty to meaningfully disclose and provide all material information about the risks and harms associated with using PROPECIA.

212. Through their labeling, advertising, marketing, promoting, publications, and/or regulatory submissions, Defendants made negligent misrepresentations of material facts regarding the safety of PROPECIA and of the dangers and risk of injuries associated with PROPECIA, including the following particulars:

a. Defendants negligently misrepresented that certain sexual side effects caused and/or associated with the use of PROPECIA were only temporary and would "go away" upon discontinuation of the drug when Defendants had reason to know, should have known, and/or were in the position to know that these sexual side effects could be chronic, despite discontinuing use of PROPECIA;

b. Defendants negligently misrepresented that certain sexual side effects caused and/or associated with the use of PROPECIA for male pattern hair loss "disappeared" in most men who continued using Defendants' product when Defendants had reason to know, should have known, and/or were in the position to know that these side effects persist and could be chronic;

c. Defendants negligently misrepresented that users should "stick with" their use of PROPECIA for male pattern hair loss despite suffering serious side effects when

Defendants had reason to know, should have known, and/or were in the position to know that these side effects persist and could be chronic;

d. Defendants negligently misrepresented that PROPECIA had been adequately tested and found safe;

e. Defendants negligently omitted and/or concealed information about the substantial risks of serious injury associated with using PROPECIA; and

f. Defendants negligently misrepresented that certain sexual side effects "went away" in men who discontinued use of PROPECIA and negligently omitted or concealed material information about the chronic nature of PROPECIA's sexual side effects from U.S. users and consumers, like Plaintiff, and U.S. physicians, including Plaintiff's physicians, despite providing warnings and instructions to foreign users and consumers of PROPECIA that certain sexual side effects could be persistent and chronic.

213. Defendants had reason to know, should have known, and/or were in the position to know that these misrepresentations of adverse information were inaccurate and misleading and that PROPECIA had defects in its design and was unreasonably dangerous.

214. Defendants negligently disregarded their obligation to provide truthful and forthright representations regarding the safety and risk of PROPECIA to consumers, including Plaintiffs, and to the medical community.

215. Further, Defendants did not have adequate proof upon which to base such representations, and in fact, given Defendants' specific knowledge about the design and formulation of PROPECIA and the reported adverse events associated with their drug, Defendants had reason to know, should have known, and/or were in the position to know that these

representations were inaccurate and misleading. Particularly, Defendants had reason to know, should have known, and/or were in the position to know that PROPECIA was unreasonably dangerous, causes serious harmful risk as described herein, and that certain sexual side effects do not "go away" with discontinuation of PROPECIA.

216. Defendants' negligent misrepresentations concerned material facts regarding the dangers, risks, safety, benefits, and utility of PROPECIA which induced Plaintiffs, Plaintiffs' physicians, and the general public to reasonably rely upon such inaccurate and misleading representations and to use PROPECIA.

217. Plaintiff and Plaintiff's physician did in fact rely upon such negligent misrepresentations to Plaintiff's detriment in that Plaintiff's physician prescribed and Plaintiff purchased and used PROPECIA. Had Defendants not negligently misrepresented such information, Plaintiff would not have ingested PROPECIA and suffered the resulting harm. Such reliance was justified and rightful under the circumstances as Plaintiff and Plaintiff's physicians were in a position in which such material misrepresentations were directed.

218. Defendants knew that without truthful and accurate information and warnings regarding PROPECIA, Plaintiffs and Plaintiffs' physicians could not make an informed choice about the risk and benefits of using PROPECIA for male pattern hair loss.

219. Defendants continue to negligently misrepresent the chronic nature of the side effects of PROPECIA by denying and downplaying the causal relationship between those side effects and their product to this very day.

220. As a result of Defendants' negligent misrepresentations of material facts upon which Plaintiff and Plaintiff's physicians have relied, Plaintiff has suffered significant and persistent and/or permanent injuries, including but not limited to, loss of libido; erectile dysfunction;

decreased semen output; orgasm and ejaculation disorders; fatigue; penile atrophy (shrinkage); and mental and emotional issues, such as anxiety and depression. Except for the negligence in Defendants' representations, Plaintiff would never have sustained the injuries alleged herein.

221. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiff sustained injuries and damages alleged herein, including severe and permanent injuries; severe emotional distress; pain and suffering; and other damages to be proved at trial.

COUNT XI
VIOLATION OF THE
OHIO CONSUMER SALES PRACTICES ACT
O.R.C. §§ 1345.01, *et seq.*
(As to Defendants Merck)

222. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth here and further allege as follows:

223. At all times material to the allegations in this Complaint, Defendants were engaged in the business of designing, testing, manufacturing, labeling, marketing, promoting, advertising, distributing, supplying, selling, and/or placing into the stream of commerce, PROPECIA, and did in fact sell and/or place into the stream of commerce, PROPECIA.

224. Defendants are suppliers under O.R.C. § 1345.01, in that Defendants are a seller or other person engaged in the business of effecting or soliciting consumer transactions.

225. Defendants have a statutory duty to refrain from unfair competition, consumer fraud, and/or unfair and deceptive acts and practices in the advertisement, promotion, sale, and/or placement into the stream of commerce of their product, PROPECIA.

226. Plaintiff purchased PROPECIA primarily for personal, family, and/or household purposes and not for resale.

227. Defendants began marketing PROPECIA in 1998 with an aggressive and deceptive promotional campaign directed at consumers.

228. Defendants engaged in unfair, deceptive, fraudulent, misleading, an unconscionable acts and/or practices in violation of O.R.C. §§ 1345.02 & 1345.03.

229. In violation of O.R.C. §§ 1345.02 & 1345.03, in the normal course of business, Defendants misrepresented the alleged benefits and characteristics of PROPECIA; suppressed, omitted, concealed, and failed to disclose material information concerning known adverse effects of PROPECIA; misrepresented and advertised that PROPECIA was of a particular standard, quality, or grade that it was not; misrepresented that PROPECIA had certain characteristics, uses, or benefits; advertised and offered for sale PROPECIA which was defective; and otherwise engaged in fraudulent, deceptive, and unfair acts and practices.

230. In violation of O.R.C. §§ 1345.02 & 1345.03, Defendants made misrepresentations, omissions, and/or concealments of material facts regarding the safety of PROPECIA and of the dangers and risks of injuries associated with PROPECIA in their labeling, advertising, marketing, promoting, publications, and/or regulatory submissions, including in the following particulars:

a. Defendants misrepresented that certain sexual side effects caused and/or associated with the use of PROPECIA were only temporary and would "go away" upon discontinuation of the drug when Defendants knew, had reason to know, and/or should have known that these sexual side effects could be chronic, despite discontinuing use of PROPECIA;

b. Defendants misrepresented that certain sexual side effects caused and/or associated with the use of PROPECIA for male pattern hair loss "disappeared" in most men who continued using Defendants' product when Defendants knew,

had reason to know, and/or should have known that these side effects persist and could be chronic;

c. Defendants misrepresented that users should "stick with" their use of PROPECIA for male pattern hair loss despite suffering serious side effects when Defendants knew, had reason to know, and/or should have known that these side effects persist and could be chronic;

d. Defendants misrepresented that PROPECIA was safe and/or omitted or concealed information about the substantial risks of serious injury associated with using PROPECIA; and

e. Defendants misrepresented that certain sexual side effects "went away" in men who discontinued use of PROPECIA and omitted or concealed material information about the chronic nature of PROPECIA's sexual side effects from U.S. users and consumers, like Plaintiff, and U.S. physicians, including Plaintiff's physicians, despite providing warnings and instructions to foreign users and consumers of PROPECIA that certain sexual side effects could be persistent and chronic.

231. Defendants' conduct misled, deceived, and damaged Plaintiff, and Defendants' fraudulent, misleading, deceptive, and unfair conduct was intended to induce Plaintiff and Plaintiff's physicians into reasonably relying on said conduct by prescribing, purchasing, and/or using PROPECIA to Plaintiff's detriment.

232. Moreover, Defendants knowingly took advantage of Plaintiff, who was reasonably unable to protect his interests due to Plaintiff's lack of knowledge of the truthfulness of Defendants' representations and of the harmful adverse side effects of PROPECIA.

233. Defendants' misrepresentations and omissions regarding the side effects of PROPECIA created a likelihood of, and in fact caused, confusion and misunderstanding in consumers, like Plaintiff, and were likely to induce in the mind of a consumer beliefs which were not in accord with the facts and likely to induce reliance by consumers, such as Plaintiff, to their detriment.

234. As a result of Defendants' conduct described herein, Plaintiff and Plaintiff's physicians in fact reasonably and/or justifiably relied upon Defendants' conduct and prescribed, purchased, and/or used PROPECIA.

235. Defendants' conduct was willful, immoral, unethical, oppressive, outrageous, unconscionable, and substantially injurious to users and consumers, like Plaintiff, and to the general public, therefore, offends the public conscience.

236. By means of the above-described deceptive trade practices, Defendants have unlawfully acquired money from numerous Ohio residents, including Plaintiff.

237. As a result of Defendants' conduct and misrepresentations, omissions, and/or concealments, Plaintiff has suffered significant and persistent and/or permanent injuries, including but not limited to, loss of libido; erectile dysfunction; decreased semen output; orgasm and ejaculation disorders; fatigue; penile atrophy (shrinkage); and mental and emotional issues, such as anxiety and depression.

238. As a proximate result of Defendants' conduct and misrepresentations, omissions, and/or concealments amounting to consumer fraud; unfair competition; and/or deceptive or unfair trade acts or practices, Plaintiff has suffered ascertainable losses, in an amount to be determined at trial.

COUNT XII
UNJUST ENRICHMENT
(As to All Defendants)

239. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows:

240. At all times material to the allegations in this Complaint, Defendants were engaged in the business of designing, testing, manufacturing, labeling, marketing, promoting, advertising, distributing, selling, and/or placing into the stream of commerce their product, PROPECIA, and did in fact sell and/or place into the stream of commerce their product, PROPECIA.

241. Plaintiff purchased PROPECIA for addressing male pattern hair loss.

242. Through his purchase and use of PROPECIA, Plaintiff has conferred an economic benefit, via monetary payments, upon Defendants.

243. Defendants appreciated and knew of the economic benefit conferred upon them through Plaintiff's purchase and use of Defendants' product and accepted and retained such benefits despite Defendants' wrongful conduct detailed above.

244. Plaintiff did not receive the safe product for which Plaintiff intended to purchase.

245. Acceptance or retention by Defendants of the economic benefit under such circumstances makes it inequitable and unjust for the Defendants to retain the benefit without payment because Plaintiff did not in fact receive the product Defendants represented PROPECIA to be.

246. Based upon the foregoing, Plaintiff is entitled to equitable relief against Defendants on account of Defendants' unjust enrichment.

COUNT XIII
LOSS OF CONSORTIUM
(As to All Defendants)

247. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows:

248. At all times material hereto, Plaintiff Bonnie Phelps has been married to Plaintiff Richard Phelps.

249. As a result of Defendants' wrongful conduct, Plaintiff Bonnie Phelps has been deprived of the consortium of her husband, Plaintiff Richard Phelps, including but not limited to, the loss of fellowship, companionship, society, attentions, services, affection, guidance, comfort and household services. Further, Plaintiffs allege their marital and domestic relationships have been impaired and negatively affected—particularly, given the nature of the chronic sexual side effects caused and associated with the use of PROPECIA. Plaintiff Bonnie Phelps has suffered great emotional pain and mental anguish. These losses are permanent and continuing in nature.

250. Additionally, Plaintiff Bonnie Phelps claims the reasonable value or expenses of hospitalization, medical, nursing care and treatment necessarily or reasonably obtained by Plaintiff Richard Phelps in the past or to be obtained in the future.

251. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff Bonnie Phelps has sustained injuries and damages alleged herein and other damages to be proved at trial.

COUNT XIV
PUNITIVE OR EXEMPLARY DAMAGES
O.R.C. § 2307.80
(As to Defendants Merck)

252. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows:

253. At all times material to the allegations in this Complaint, Defendants were engaged in the business of designing, testing, manufacturing, labeling, marketing, promoting, advertising, distributing, selling, and/or placing into the stream of commerce their product, PROPECIA, and did in fact sell and/or place into the stream of commerce their product, PROPECIA.

254. At all times material, Defendants knew and/or recklessly and flagrantly disregarded the fact that PROPECIA causes chronic side effects that far outweigh the benefit of using PROPECIA for male pattern hair loss.

255. At all times material, Defendants attempted to and did misrepresent, omit, and/or conceal material facts concerning the safety of PROPECIA from users and consumers, like Plaintiff; the medical community, including Plaintiff's physicians; the general public; and the FDA, as detailed herein.

256. Despite the foregoing, Defendants continue to aggressively market PROPECIA to consumers, including Plaintiff, and physicians to this very day, without disclosing the risk of serious chronic side effects.

257. Moreover, Defendants' aggressive advertising and marketing campaign, coupled with Defendants' intentional concealment and/or reckless failure to disclose the true nature of the chronic side effects caused and/or associated with use of PROPECIA, were deceptively intended to incentivize long-term use of PROPECIA and to discourage users from discontinuing use of the drug despite suffering from serious sexual side effects, as alleged herein. Particularly, Defendants represented that certain sexual side effects were only temporary and would "go away" upon discontinuing use of PROPECIA and would "disappear" in most men who continued use of PROPECIA.

258. Defendants knew of PROPECIA's defective and unreasonably dangerous nature, as set forth herein, but continued to design, manufacture, advertise, market, promote, distribute, and/or sell PROPECIA so as to maximize sales and profits at the expense of public health and safety, including Plaintiff, in flagrant; conscious; deliberate; and/or reckless disregard of the foreseeable harm caused by the PROPECIA.

259. Defendants intentionally concealed and/or recklessly failed to disclose to consumers, including Plaintiff; to physicians, including Plaintiff's physicians; and to the general public the chronic side effects of PROPECIA in order to maximize Defendants' profits through continued and increased sales of PROPECIA.

260. Moreover, Defendants continue to misrepresent the chronic nature of the side effects of PROPECIA by denying and downplaying the causal relationship between those side effects and their product to this very day.

261. Further, even when Defendants were ordered by the FDA to issue a label change suggesting the relationship between PROPECIA and chronic side effects, Defendants immediately diluted those changes by publicly denying that PROPECIA caused any of the harmful chronic side effects described herein.

262. Defendants' intentional and/or reckless failure to disclose pertinent and/or material information relating to PROPECIA deprived Plaintiff and Plaintiff's physicians of the information necessary to enable Plaintiff and Plaintiff's physicians to weigh the true risks of using the PROPECIA against its benefits.

263. As a result of Defendants' conduct, Plaintiff did in fact suffer injuries and damages. Particularly, Plaintiff has suffered significant and persistent and/or permanent injuries, including but not limited to, loss of libido; erectile dysfunction; decreased semen output; orgasm and

ejaculation disorders; fatigue; penile atrophy (shrinkage); and mental and emotional issues, such as anxiety and depression.

264. As a direct and proximate result of Defendants' conscious, deliberate, flagrant, malicious, and/or reckless disregard for the rights and safety of the public and of consumers, such as Plaintiff, Plaintiff suffered severe and permanent injuries. Plaintiff has endured substantial pain and suffering and has otherwise been physically and emotionally injured. Plaintiff's injuries and damages are permanent and will continue into the future.

265. Pursuant to O.R.C. § 2307.80, because Defendants' conduct detailed herein was committed with conscious, deliberate, flagrant, malicious, and/or reckless disregard for the rights and safety of the general public and users and consumers, including Plaintiff; punitive or exemplary damages should be assessed against Defendants in an amount deemed appropriate by the jury to deter such future wrongful conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, Richard Phelps and Bonnie Phelps, request judgment against the Defendants in an amount to be determined at trial to include, but not be limited to:

A. Compensatory damages, including without limitation past and future medical expenses; past and future pain and suffering; past and future emotional distress; past and future loss of enjoyment of life; and consequential damages;

B. Damages under the Ohio Consumer Sales Practices Act;

C. Loss of consortium damages;

D. Punitive or exemplary damages in an amount sufficient to punish Defendants and set an example;

E. Disgorgement of profits;

F. Restitution;

G. Costs and fees of this action, including reasonable attorney's fees;

H. Prejudgment interest and all other interest recoverable; and

I. Such other additional and further relief as this Court deems Plaintiff may be entitled to in law or in equity.

Dated this 25th day of January, 2013.

Respectfully submitted,

Theodore E Laszlo, Jr. (OH #0009531)
Jeffrey O. Klein (OH #0082724)
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COUNSELS FOR PLAINTIFFS

JURY TRIAL DEMAND

Plaintiffs demand a trial by jury as to all counts and issues in the above matter.

Theodore E Laszlo, Jr.
Jeffrey O. Klein

Counsels for Plaintiffs